IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor: Tara Nylese Attorney Docket No. 10442-004

Application No.: 10/530,464 Art Unit: 1641

Filed: 04/05/2005 Examiner: Jacqueline A. Diramio

For: Portable Diagnostic Device And Method For Determining Temporal Variations In Concentrations

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

May 1, 2007

TRANSMITTAL OF APPELLANT'S AMENDED BRIEF UNDER 37 CFR 41.37

Sir:

This paper is in response to the Office Action mailed April 17, 2007 requiring submittal of an amended appeal brief in full conformity with 37 CFR 41.37. The amended brief containinbg appropriate headings and references to an Evidence Appendix and a Related Proceedings Appendix is submitted herewith.

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I HEREBY CERTIFY that this Response To Office Action is being FAXED to the U.S. Patent Office at 571-273-8300 (Central Fax Number) on this 1st day of May, 2006.

Ferdinand M. Romano
Ferdinand M. Romano

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PATENT

Attorney Docket No. 10442-004

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor:	Tara Nylese	)	Group Art Unit: 1641
Serial No.:	10/530,464	)	Examiner: Jacqueline A. Diramo
Filed:	04/05/2005	)	

Title: Portable Diagnostic Device And Method For Determining Temporal Variations In Concentrations

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S AMENDED BRIEF UNDER 37 CFR 41.37

Sir:

This brief is in furtherance of the Notice of Appeal filed December 19, 2006, in response to the final rejection in this application mailed on September 22, 2006 and fully responsive to the Notification mailed on April 4, 2007 by the Patent Appeal Center Specialist.

Please proceed to the following page.

Serial No. 10/530,464

Atty. Doc. No. 10442-004

1. REAL PARTY IN INTEREST - 37 CFR 41.37(c)(1)(i)

The real party in interest in this Appeal is the Tara Nylese.

2. RELATED APPEALS AND INTERFERENCES - 37 CFR 41.37(c)(1)(ii)

There is no other appeal, interference or judicial proceeding that is related to or that will directly affect, or that will be directly affected by, or that will have a bearing on the Board's decision in this Appeal.

3. STATUS OF CLAIMS - 37 CFR 41.37(c)(1)(iii)

Claims 1 – 24 are pending in the application. Claims 2 – 9 and 22 – 24 are withdrawn from consideration based on a restriction requirement. Claims 1 and 10 – 21 have been finally rejected and are the subject of this appeal. A copy of the claims is attached hereto in the Claims Appendix. Appellant respectfully appeals the final rejection of claims 1 and 10 - 21.

4. STATUS OF AMENDMENTS - 37 CFR 41.37(c)(1)(iv)

One amendment was filed subsequent to the final rejection, on December 5, 2006. The amendment was filed to overcome objections raised to claims 1 and 13 in the final office action. The amendment was entered per the Advisory Action mailed 12/29/2006 and the objections raised for claims 1 and 13 were overcome. Otherwise, the claims stand rejected based on the same art rejections and reasons presented in the Final Office Action mailed 9/27/2006.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER- 37 CFR 41.37(c)(1)(v)

5A. BRIEF BACKGROUND PROVIDING CONTEXT FOR THE SUMMARY OF CLAIMED SUBJECT MATTER

Tracking of variable chemical concentrations in fluids is key to monitoring health, medical and environmental conditions. This data can identify deleterious trends, enabling prompt awareness which is often essential for timely intervention. In the past, such monitoring has required complex, laboratory-based assay methodologies. Yet it is desirable to provide simplified analysis procedures in order that changes in chemical concentrations, such as hormone levels, are more conveniently and quickly assessed.

By way of example, it is common to assess the health of a pregnancy during the first trimester by quantitatively assessing changes in blood level concentration of chorionic gonadotrophin (hCG). Typically, hCG levels will double every two to three days for a normal pregnancy while absence of a consistent increase may be suggestive of a miscarriage or an ectopic pregnancy. The only generally accepted method of monitoring hCG levels on multiple occasions, e.g., one to two days apart, has been through performance of quantitative laboratory tests, requiring that patients make multiple visits to have blood drawn. Such quantitative tests cannot be performed in a home environment and there is usually a delay of at least 24 hours before each set of results becomes available. There is a need to provide rapid and reliable screening tests for assessing conditions, including but not limited to the health of a pregnancy.

(iii) providing a second test unit (See Fig 10) including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels 44b (See page 5, lines 5-6, and page 11, lines 20-27);

(iv) providing a first sample from the source (See page 5, lines 6-9);

(v) bringing the first sample into contact with the first unit 210 to allow the first region 42a thereon to indicate 44a whether analyte is present in the sample at at least the first level (See page 5, lines 6-9);

(vi) providing a second sample from the source on an occasion subsequent to providing the first sample (See page 5, lines 9-11); and

(vii) bringing the second sample into contact with the second unit 210 to allow the first region 42a thereon to indicate 44b whether analyte is present in the second sample at at least the second level (See page 5, lines 9-11).

According to independent claim 20, a method for monitoring changes in analyte level of a source, includes:

(i) providing two or more test units (*210, see FIG 10*) each including multiple regions (*42a, 42b, 42c, 42d*) thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable (*44a, 44b, 44c or 44d*) from another region (*44a, 44b, 44c or 44d*) in the same test unit (*See page 4, lines 7-9*);

(ii) bringing a first sample from the source into contact with a first of the units (*210*) to allow one or more of the regions (*42*) thereon to indicate whether the analyte is present in the sample at at least one of the levels (*44, see page 4, lines 9-12*); and

(iii) on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units (*210*) to allow one or more of the regions (*42*) thereon to indicate whether the analyte is present in the second sample at at least one of the levels (*44, see page 4, lines 12-15*).

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5B. CONCISE EXPLANATION OF SUBJECT MATTER DEFINED IN EACH INDEPENDENT CLAIM

The following references exemplary embodiments described in the Specification and which are covered by specific claims, but it is to be understood that the claims are not so limited in scope.

According to independent claim 1, a method for monitoring temporal changes of analyte levels in a source (see page 19, lines 17-18) includes

(i) providing multiple unitary test devices (See devices 210 of the kit 200 shown in FIGS 10 and 11 as well as page 18, lines 12-27), each unitary test device (210) including a plurality of regions (See membranes 42 of FIGS 2 and 7 and page 11, lines 9-13, page 16, lines 14-19), each region responsive at a different sensitivity level (See page 11, lines 9-13) to indicate presence of the analyte in the source (See page 19, lines 30- page 20, line 2);

(ii) bringing a sample from the source into contact with a first of the unitary test devices (*210*) to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions (*42*) of the first test device (*See page 20, lines 2 – 4*);

(iii) subsequently bringing a different sample from the same source into contact with a second of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions (*42*) of the second unitary test device, (*See page 20, lines 5 - 8*) said responses providing information about temporal change in analyte concentration (*See page 20, lines 10-15*).

According to independent claim 10, a method for monitoring changes in analyte level of a source includes:

(i) defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source (See page 5, lines 1-3);

(ii) providing a first test unit 210 (See Fig 10) including a first region 42a thereon responsive to the presence of analyte in the source at a first of the sensitivity levels 44a (See page 5, lines 3-5, and page 11, lines 20-27);

6. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL - 37 CFR 41.37(c)(1)(vi)

Claims 10 – 16 and 19 – 21 have been rejected under 35 U.S.C. Section 102 as being anticipated by Boehringer et al. (WO98/39657).

Claims 10, 19 and 20 have been rejected under 35 U.S.C. Section 102 as being anticipated by Kenjyou et al. (US 2004/0096985).

Claim 1 has been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boehringer et al. (WO98/39657) or Kenjyou (US 2004/0096985) in view of Toranto et al. (US 2003/0175992).

Claims 17 and 18 have been rejected under 35 U.S.C. Section 103(a) as being unpatentable over Boehringer et al. (WO98/39657) in view of Cole (U.S. 6,656,745).

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7. ARGUMENT 37 CFR 41.37(c)(1)(vii)

7A. APPELLANTS TRAVERSE ALL REJECTIONS BASED ON THE BOEHRINGER OR THE KENJYOU REFERENCE, WHETHER ALONE OR IN COMBINATION WITH THE TORANTO REFERENCE OR THE COLE REFERENCE. PATENTABILITY OF EACH CLAIM SHOULD BE SEPARATELY CONSIDERED.

In the following argument, Section 7B, it is demonstrated that each of the rejections of claims 10-16 and 19-21 under section 102 is deficient because none of these claims can be read upon either the Boehringer reference or the Kenjyou reference. To facilitate understanding of the differences between each of these two references and the claimed invention, a brief discussion is provided which describes the references.

In Section 7C Appellant demonstrates that each of the rejections of claims 1, 17 and 18 under section 103 is improper because: (i) none of the art of record can be combined to provide the claimed subject matter; and (ii) the Examiner's combinations require a reconstruction of the prior art which is not taught or suggested, and which is inconsistent with the teachings of references.

In Section 7D Appellant argues that each of the claims depending from claims 10 and 20 and rejected under Section 102 defines distinct and non-obvious subject matter.

Appellant urges that patentability of each claim should be separately considered. All of the claims are separately argued. Claims 11 – 19 depend from independent claim 10 and claim 21 depends from independent claim 20. All of the dependent claims 11 – 19 and 21 have been rejected, either under Section 102 based solely on the Boehringer reference or the Kenjyou reference, or under Section 103 based on a combination of the Boehringer reference or the Kenjyou reference in combination with either the Toranto reference or the Cole reference.

General argument, based on deficiencies in the rejection of independent claims 10 and 20 under Section 102 demonstrates patentability of claims 11 – 19 and 21. However, none of the rejected claims stand or fall together because each claim further defines a unique combination that patentably distinguishes over the art of record. For this reason, the Board is requested to consider each argument presented with regard to each dependent claim. Argument demonstrating

patentability of each dependent claim is presented under subheadings identifying each claim by number.

7B. ALL REJECTIONS OF THE INDEPENDENT CLAIMS 10 AND 20 UNDER SECTION 102, WHETHER BASED ON THE BOEHRINGER REFERENCE OR BASED ON THE KENJYOU REFERENCE, ARE IN ERROR.

7B(i) THE REJECTIONS OF CLAIMS 10 AND 20 UNDER SECTION 102 BASED ON THE BOEHRINGER REFERENCE ARE IN ERROR.

The Appellant traverses the rejections of claims 10 and 20 under 35 USC 102(b) based on the Boehringer reference. As fully argued herein, the Boehringer reference fails to disclose each and every element as set forth in each of the independent claims 10 and 20. This deficiency renders the rejections based on the Boehringer reference under Section 102 improper.

BRIEF DISCUSSION OF THE BOEHRINGER REFERENCE

As described in the Summary of the Invention, the Boehringer reference discloses methods, devices and kits for visually quantifying the amount of analyte in a sample. FIGS 2 and 3 are illustrative of a single device which includes multiple test regions 16. In FIG 2, multiple separate matrices or regions each define a flow path emanating from a common sample zone Barrier or threshold levels are set for each region to assess concentration of analyte when portions of the sample are applied among the multiple zones. See pp. 25 – 26 of the reference. In FIG 3, there is shown a "multi-flow path device" in which each flow path utilizes a different concentration of soluble antibody to facilitate creation of a different threshold response level for purposes of quantitation. See page 28. As stated at page 28, "soluble antibody concentrations and barrier zone break-through thresholds could be used to modulate the response ... of each flow path and facilitate quantitation." The text at pp 28-29 goes on to state that this is useful when concentration of analyte in a sample occurs over a wide dynamic range such that

"at low analyte concentrations color wioll only appear on flow paths having low concentrations of soluble antibody ... [but] as analyte concentration increases, color will also appear on detection zones on flow paths having higher amounts of soluble antibody."

Based on these excerpts, Appellant urges that it is accurate to characterize the Boehringer reference as concerning quantitation of analyte concentration levels from a single source, with portions of the source being concurrently provided along each of the several flow paths so as to identify and count a number of visual responses among the multiple flow paths. Accordingly, it is possible to visually assess relative concentration of analyte in the source by observing the number of colored lines appearing on the test units in a single device. To the extent the reference uses the term sample with regard to different receiving zones it is only in the context of providing portions of the same sample in different zones, e.g., portions of the source taken on the same occasion from a single source and applied concurrently along multiple flow paths to observe or count a number of lines or colored zones. The number of lines or zones can be correlated with analyte concentration in the sample based on a calibration methodology. See, also, p. 31, lines 1 – 12.

The Boehringer reference only addresses quantitation of analyte concentration relative to a single device such as shown in the figures, e.g., FIG 2. This reference does not at all disclose, imply or suggest any methodology relating to the change in an analyte concentration level over time, e.g., based on obtaining samples from the same source on different occasions. As an example, the above-discussed needs to monitor hCG levels for purposes of assessing health of a pregnancy are not at all contemplated by the Boehringer reference.

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7B(i) Cont'd

THE REJECTION OF CLAIM 10 BASED ON THE BOEHRINGER REFERENCE IS IN ERROR.

Claim 10, a method for monitoring changes in an analyte level of a source requires the following combination wherein the claimed test units may each correspond to each in a pair of units according to any one of the embodiments illustrated in FIGS 1 – 9:

> defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;
>
> providing a first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels;
>
> providing a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;
>
> providing a first sample from the source;
>
> bringing the first sample into contact with the first unit to allow the first region thereon to indicate whether analyte is present in the sample at at least the first level;
>
> providing a second sample from the source on an occasion subsequent to providing the first sample; and
>
> bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level.

This rejection of claim 10 is premised on a conclusion that claim 10 can be read upon the Boehringer reference, but in response to the intial rejection based on Boehringer et al. claim 10 has already been further distinguished, by way of an amendment filed on 14 July 2006. Claim 10 specifies that the second sample is brought into contact with the second unit to indicate whether analyte is present "in the second sample" at at least the second level.

The outstanding rejection as applied to both claim 10 and claim 20 (see pages 4 and 5 of the Final Office Action) urges that the claimed feature of

"bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level ..."

is found in the Boehringer reference. For this contention, the rejection relies on a large number of citations in the Boehringer reference:

FIG 3; page 4, lines 22-38; page 5, lines 1 – 2; Page 6, lines 26 – 34; page 13, lines 27 – 37; page 14, lines 6 – 27; page 15, lines 29 – 32; page 23, lines 7 – 25; page 29, lines 35 -- 38; page 30, lines 1 – 21; example 6 at page 48 and text under the heading "MULTIPLE LANE LATERAL FLOW TEST DEVICES" at pages 52 – 54.

However, these citations do little more that identify a device which might be suitable as a test unit to practice the claimed method and this certainly falls short of aniticipating the claimed method. The rejection cites these numerous passages and examples from the Boehringer reference, but none of these, alone or in combination, teach or suggest

"bringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level ..."

teaches the concept of using multiple test units to assess temporal variations in analyte levels obtained from a source on different occasions. Claim 10 so defines this feature by reciting that the second sample is obtained

"on an occasion subsequent to providing the first sample"

and reciting

"bringing the second sample into contact with the second [test] unit"

The Boehringer reference fails to teach or suggest temporal monitoring of analyte levels with test kits. As already explained, with respect to hCG levels, the only generally accepted method of monitoring hCG levels on multiple occasions has been through performance of quantitative laboratory tests, requiring that patients make multiple visits to have blood drawn. There is no prior art suggesting the use of test kits for measuring changes in analyte levels. The Boehringer reference makes no disclosure relating to measurement of temporal variations in analyte levels.

The rejection also cites lines 27 – 37 at page 13 of the Boehringer reference, but at best this has no relation to the claimed subject matter. The cited passage does include the words "inspect the strip at different time points" (see line 30 – 31) but this is in reference to a single strip on one device and has no relation to measurement of a sample provided "on an occasion subsequent to providing the first sample ..." As further explained in the same paragraph of the Boehringer reference, this feature (as well as correlating "the number of lines at which color is produced at different times with the amount of analyte in the sample [lines 31 – 33] simply relates to allowing "the user to visually determine the analyte concentration by comparison to the chart ..." See lines 36 – 37. This passage has nothing to do with the invention of claim 10, which requires providing an indication as to

"whether analyte is present in the second sample at at least the second level ..."

It is not seen how any of the text cited at page 14, lines 6 – 27 or at page 15, lines 29 – 32 is supportive of the rejection and if the Examiner still believes otherwise, explanation is requested. The invention of claim 10 requires at least two test devices, while for each of the embodiments disclosed in the Boehringer reference there is shown only a single device. For

In this regard, an analysis of the many cited passages is now presented to confirm the deficiency of the Boehringer reference.

FIG 3 only illustrates a single "multi-flow path device" 11 (see page 29, lines 34 – 37) which is described as a format similar to that of the single device of FIG 2, described at page 25, lines 19 ff. The reference fails to disclose or suggest Appellant's method of claim 10 in conjunction with the description of any figures. With regard to FIG. 3, which the rejection relies upon, a line-by-line reading of the text beginning at page 29, line 34 provides no evidence to the contrary. Clearly, there is no disclosure in the Boehringer reference relating to the possibility of obtaining first and second samples from a given source wherein the second sample is obtained

"on an occasion subsequent to providing the first sample"

Claim 10 further requires the combination of

bringing the first sample into contact with the first unit

and

bringing the second sample into contact with the second unit

The combination of claim 10 further enables determination of a different indication of concentration for each sample:

(1) an indication as to

"whether analyte is present in the sample at at least the first level"

and

(2) an indication as to

"whether analyte is present in the second sample at at least the second level ..."

Citation of lines 22 – 38 at page 4, lines 1 – 2 at page 5, and lines 26 -34 at page 6 of the Boehringer reference provides no support for the rejection. These disclosures describe no more than what Appellant readily acknowledges as prior art: use of a device for determining an amount of analyte in a sample. This is not the claimed invention. It is only the applicant who

example, the lines 16a, 16b and 16c described at page 15 are shown to reside on the single device of FIG 1.

The citation of page 23, lines 7 – 25 is not seen to have any relation to the rejection of claim 10. The Citation at pages 29 and 30 has already been addressed. Example 6 at page 48 does not support the rejection either. Although the text alludes to application of test solutions to record time "for appearance of first visually detectable red latex at each of the test bands" (see lines 24 – 27 at page 48), there is absolutely no disclosure relating to

> "providing a second sample from the source on an occasion subsequent to providing the first sample"

or the combination of

> "bringing the first sample into contact with the first unit"

and

> "bringing the second sample into contact with the second unit"

The citation of the text at pages 52 – 54 concerning multiple lane lateral flow test devices discusses aspects of the test devices of FIGS 1, 2 and 3 but does not provide any support for rejecting claim 10.

Still another feature not disclosed or suggested in the Boehringer reference is that claim 10 enables determination as to whether

> "analyte is present in the [first] sample [from the source] at at least the first level"

and whether

> "analyte is present in the second sample at at least the second level."

In conclusion, although the rejection cites numerous passages and examples from the reference, it has been demonstrated that none of these, alone or in combination, teach or suggest the following combination of claim 10:

providing a first test unit...
providing a second test unit ...
providing a first sample from the source ...
bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level ...
providing a second sample from the source on an occasion subsequent to providing the first sample ...
bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level.

Mere identification of a device which might be suitable as a test unit with which to practice the claimed invention falls short of aniticipating the claimed method. For all of these reasons the rejection of claim 10 based on the Boehringer reference is without support and is clearly in error. Nothing in the reference anticipates or suggests the claimed invention. If the examiner disagrees, then it is incumbent upon the examiner to come forward citations which support aniticipation or obviousness. It is requested that the rejection of claim 10 under Section 102 be withdrawn.

7B(i) Cont'd

THE REJECTION OF CLAIM 20 BASED ON THE BOEHRINGER REFERENCE IS ALSO IN ERROR

The rejection of Claim 20 under Section 102 based on the Boehringer reference is also deficient because the Boehringer reference also fails to disclose each and every element as set forth in the independent claim 20. Claim 20 is distinguished over the Boehringer reference for reasons similar to those described with regard to claim 10.

Specifically, claim 20 requires the following combination of features:

"... on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels."

Although the subject matter of claim 20 is substantively different from that of claim 10, the examiner has relied upon the same passages to reject claim 20 as for the rejection of claim 10:

FIG 3; page 4, lines 22-38; page 5, lines 1 – 2; Page 6, lines 26 – 34; page 13, lines 27 -- 37; page 14, lines 6 – 27; page 15, lines 29 – 32; page 23, lines 7 – 25; page 29, lines 35 – 38; page 30, lines 1 – 21; example 6 at page 48 and text under the heading "MULTIPLE LANE LATERAL FLOW TEST DEVICES" at pages 52 – 54.

The above review of these same passages for claim 10 is equally applicable to claim 20 and demonstrates that the Examiner's citations from the Boehringer reference fail to provide the above-quote subject matter of claim 20. Indeed claim 20 includes numerous other features which are also absent from the Boehringer reference. Examples now follow:

The Boehringer reference does not teach or suggest

"providing two or more test units each including multiple regions thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from another region in the same test unit"

In contrast to the above, the Boehringer reference only discloses a single use of a device such as shown in FIG 3. Nor does the Boehringer reference teach or suggest, after providing a first sample,

"on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels."

There is no basis to read this quoted subject matter on the Boehringer reference and, therefore, it cannot be said that the claim is anticipated by Boehringer et al. None of the prior art teaches or suggests monitoring changes in analyte level of a source with two or more test units. As already explained, with respect to hCG levels, the only generally accepted method of monitoring hCG levels on multiple occasions has been through performance of quantitative laboratory tests, requiring that patients make multiple visits to have blood drawn. There is no prior art suggesting the use of test kits for measuring changes in analyte levels. The Boehringer reference makes no disclosure of temporal variations in analyte levels.

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7B(ii) THE REJECTION OF CLAIMS 10, 19 AND 20 UNDER SECTION 102 BASED ON THE KENJYOU REFERENCE IS ALSO DEFICIENT BECAUSE THE KENJYOU REFERENCE ALSO FAILS TO DISCLOSE EACH AND EVERY ELEMENT AS SET FORTH IN EACH OF THE CLAIMS 10, 19 AND 20.

BRIEF DISCUSSION OF THE KENJYOU REFERENCE

As more fully explained below, the Kenjyou reference, like the Boehringer reference, describes a device that may be used for qualitative or quantitative analysis of a single sample. This reference describes the use of multiple tests, but only for calibration purposes, employing several calibration samples each having a known concentration of analyte in order to associate a visible signal intensity with a known concentration. That is, standards and intensities can be used to develop a calibration curve useful for determining an unknown analyte concentration in a sample. The Kenjyou reference, like the Boehringer reference, only addresses quantitation of analyte concentration relative to a single device.

More specifically, the Kenjyou reference addresses the problem of prozone phenomenon wherein "an analyte concentration cannot be unambiguously determined with respect to a signal intensity attributed to a specific binding reaction." Par. [0008]. More specifically, "when an excessive amount of analyte is present ... the signal intensity obtained [and] attributed to the specific binding reaction does not reflect the amount of the analyte in the sample." Par. [0009] To address this problem the reference discloses a device of FIG 2, which is a single strip "where a plurality of units ... are arranged." See Par. [0041].

As stated at Par. [0015] of the Kenjyou reference, with these multiple units on one strip, "the specific binding reaction [occurs] under a different condition in each of the reaction fields." Par. [0031] again confirms that the invention of the Kenjyou reference "relates to a specific binding analysis method for qualitatively or quantitatively analyzing an analyte in a sample, using a ... device which comprises ... a plurality of reaction fields ..."

The foregoing passages of the Kenjyou reference confirm that the reference only addresses analyzing analyte in <u>one</u> sample. This reference does not at all disclose, imply or suggest any methodology relating to the change in an analyte concentration level over time, e.g., based on obtaining samples from the same source on different occasions.

THE REJECTION OF CLAIM 10 BASED ON THE KENJYOU REFERENCE IS IN ERROR.

The Kenjyou reference has been applied to claims 10, 19 and 20, but this reference does not anticipate or even suggest the claimed invention. With regard to each of these claims the rejection states that the reference discloses bringing "the second sample into contact with the second unit to provide the first region thereon an opportunity to indicate presence of analyte in the sample at at least the second level.

The rejection of claim 10 cites FIG 2 and the following paragraphs of the Kenjyou reference in support thereof:

[0015], [0019], [0021], [0027], [0059], [0061], [0070], [0076], [0080], [0123], [0131], [0143] – [0145], [0161], [0165], [0189] and [0193].

However, this combination of citations does not support anticipation of claim 10. The foregoing passages of the Kenjyou reference quoted or cited by Appellant confirm that the reference addresses analyzing analyte in one sample. The Kenjyou reference says nothing about

> "providing a first sample from the source"

and

> "providing a second sample from the source on an occasion subsequent to providing the first sample"

or about

> "bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level"

and

> "bringing the second sample into contact with the second unit ... to indicate whether analyte is present in the second sample at at least the second level."

Par. [0059], while cited in support of the rejection, actually also distinguishes the disclosure of Kenjyou from the claimed invention, disclosing a "device comprising a plurality of units ..." It is understood that the Kenjyou reference discloses one device having multiple test units thereon in order to provide "a plurality of reaction fields ..." as stated at Par [0031]. See, also, Par. [0076] which states:

"in the present invention, the analyte in the in the sample may be qualitatively or quantitatively analyzed by adjusting ... the binding substance ... in each of the reaction fields ..."

The same Par [0076] also suggests using a device such as the device of FIG 2 to "simultaneously detect a plurality of analytes ..." However, none of the foregoing is suggestive of Appellant's invention.

The Examiner has cited additional passages in the Kenjyou reference which do not support the rejection. For example, Par [0161] discusses use of multiple hCG concentrations, but as noted at Par [0166], "the purpose of doing so is to create a graph which characterizes "the relationships between the hCG concentrations and the signal intensities in the detection zones ..." This appears to be no more that correlation for purposes of calibration. The reference is devoid of any suggestion for

> "providing a second sample from the source on an occasion subsequent to providing the first sample"

and

> "bringing the second sample into contact with the second unit ... to indicate whether analyte is present in the second sample at at least the second level."

Reference to other passages in the Kenjyou reference, i.e., [0080], [0123], [0131], [0143] – [0145], [0161], [0165], [0189] and [0193], do not at all compensate for the above-noted deficiencies.

In summary, claim10 includes numerous distinctions such that the Kenjyou reference cannot anticipate the claim. Specifically, the reference fails to disclose or suggest providing a "first sample from the source" and providing a "second sample from the source on an occasion subsequent to providing the first sample ..." as required by claim 10.

Claim 10 uniquely requires the following combination which is not present in the Kenjyou reference:

> providing a first sample from the source ...
>
> bringing the first sample into contact with the first unit ... to indicate whether analyte is present in the sample at at least the first level ...
>
> providing a second sample from the source on an occasion subsequent to providing the first sample ... [and]
>
> bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level.

To demonstrate anticipation each element of this claimed method must be found in the reference. The reference clearly does not disclose or suggest:

> providing a second sample from the source on an occasion subsequent to providing the first sample ... [and]
>
> bringing the second sample into contact with the second unit to indicate whether analyte is present in the second sample at at least the second level.

For all of these reasons the rejection of claim 10 under Section 102 based on the Kenjyou reference should be overturned.

7B(ii) Continued

THE REJECTION OF CLAIM 19 WHICH DEPENDS FROM CLAIM 10 BASED ON THE KENJYOU REFERENCE IS IN ERROR.

The method of Claim 19 is also distinguished over the Kenjyou reference, requiring:

that the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions.

Claim 19 further distinguishes the method because it includes but is not limited to embodiments wherein the method can be practiced with only one responsive region defined in the first test unit and only one responsive region defined in the second test unit.

THE REJECTION OF CLAIM 20 BASED ON THE KENJYOU REFERENCE IS IN ERROR.

Claim 20 was rejected over the Kenjyou reference based on several passages relied upon to reject claim 10: [0143] – [0145], [0189] and [0193]. However, these passages are insufficient for establishing anticipation. For example, claim 20 is also distinguished over the Kenjyou reference, because it requires:

"... on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels."

None of the disclosure of the Kenjyou reference teaches or suggests this feature of claim 20. For all of these reasons the rejection of claim 20 under Section 102 based on the Kenjyou reference is in error and withdrawal is requested.

7C. EACH OF THE REJECTIONS OF CLAIMS 1, 17 AND 18 UNDER SECTION 103 IS IMPROPER BECAUSE: (I) NONE OF THE ART OF RECORD CAN BE COMBINED TO PROVIDE THE CLAIMED SUBJECT MATTER; AND (II) THE EXAMINER'S COMBINATIONS REQUIRE A RECONSTRUCTION OF THE PRIOR ART WHICH IS INCONSISTENT WITH THE TEACHINGS OF REFERENCES.

7C(i) THE REJECTION OF CLAIM 1 UNDER SECTION 103 IS IMPROPER.

This rejection of claim 1 is premised on the incorrect conclusion (explained above with reference to the rejections of claims 10 and 20 under Section 102) that the Boehringer reference and the Kenjyou reference each "teach" methods that include

"subsequently bringing a different sample from the source into contact with a second of the test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more test regions of the second test device." [Final Office Action, Pages 9 – 10]

The rejection goes on to state that both references

"fail to teach the monitoring ... of temporal changes in analyte levels or concentration."

First, with regard to all of the rejections, it is urged that, at best, Boehringer and Kenjyou only disclose bringing the "same" sample from a source while Appellant teaches bringing different samples from a source on different occasions. Moreover, the rejection is contradictory in that the rejection under Section 103 expressly concedes that both references fail to teach the monitoring ... of temporal changes. Yet there is no ambiguity in the language of claims 10 and 20 which require providing samples on different occasions. It is not clear what distinction the Examiner wishes to make, but "different occasions" are events occurring at different times. Neither the Boehringer reference nor the Kenjyou reference suggest "subsequently bringing a different sample from the source into contact with a second of the test devices ..."

Claim 1, a method for monitoring temporal changes of analyte levels in a source, requires:

> providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;
>
> bringing a sample from the source into contact with a first of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the first test device;
>
> subsequently bringing a different sample from the same source into contact with a second of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second unitary test device, said responses providing information about temporal change in analyte concentration.

The rejection of claim 1 is also premised on at least three incorrect interpretations of the primary references, which are presented at pages 8, 11 and 12 of the Final Office Action:

(i) that the Boehringer reference and the Kenjyou reference teach methods for monitoring changes in analyte levels in a sample source;

(ii) that the Boehringer reference and the Kenjyou reference teach "providing multiple test devices" and

(iii) that the Boehringer reference and the Kenjyou reference teach "bringing a different sample from the source into contact with a second of the test devices."

The Final Office Action also confirms at page 12 that both the Boehringer reference and the Kenjyou reference fail to teach the monitoring of temporal changes in analyte levels. While this admission is inconsistent with the rejections made of claims 10 and 20 under Section 102, a more significant concern with respect to rejection of claim 1 is that, in view of the above three incorrect interpretations of the primary references, the examiner's combination must be a hindsight and piecemeal reconstruction of the invention.

The combination results from a search among references for individual elements which can be assembled to suggest that the claimed method is obvious. But absent the teachings of the Appellant, the claimed invention would not exist. This is because neither the Boehringer reference nor the Kenjyou reference are at all concerned with the problem addressed by the

present invention. Further, Toranto et al. teach away from the devices of both the Boehringer reference and the Kenjyou reference. The Toranto reference teaches that it is desirable to store multiple assay tests which are single assay devices (not of the type having a plurality of regions each responsive at a different sensitivity level) because the single assay devices of Toranto et al. are small, easy to use, suitable for flexible use and storable in the delivery systems of FIGS 3 and 4. See Pars [0055] and [0056].

None of the embodiments of Toranto et al. are consistent with the devices according to claim 1 or consistent with the devices of either the Boehringer reference or the Kenjyou reference because Toranto et al. teach, with reference to FIGS 3 and 4, a compartment 44 that holds "multiple assay tests ..." wherein individuals may use more than one test on a given occasion to determine whether their analyte concentration has dropped. This flexibilty is inconsistent with the Boehringer reference and the Kenjyou reference.

Applicant claims a method in which each "test device" includes "a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source ..." The Toranto reference teaches away from such a test unit. Instead of desiring a device with a plurality of regions having different levels of sensitivity the Toranto reference only teaches individual assay tests that are small and suitable for flexible use in combination with a storage delivery system. See, again, Pars [0055] and [0056]. Therefore the Toranto reference should not be combined with the Boehringer reference or the Kenjyou reference.

Toranto et al. recognizes a different need, inconsistent with the Boehringer reference and the Kenjyou reference:

"because individuals may use more than one [test] on a given occasion, for example, to determine if their analyte concentration has dropped over time, the delivery system stores multiple assay tests." See Par. [0059].

For all of the above reasons, Toranto et al. would have no motivation to employ the devices of the Boehringer reference or the Kenjyou reference.

7C(ii) THE REJECTION OF CLAIM 17 UNDER SECTION 103 IS IMPROPER.

This rejection of claim 17 is improper for reasons in addition to the reasons presented for allowability of claims 10, 15 and 16 from which it depends.

Claim 17 requires that:
"the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level."

The rejection based on the Boehringer reference in view of Cole relies upon the Cole reference to show one of three regions responsive to "substantially the same sensitivity level" but the Cole reference does not teach or suggest use of multiple devices and therefore the combination does not result in the invention of claim 17. Further, it is believed that the combination required to meet the terms of these claims is a hindsight reconstruction of the prior art.

7C(iii) THE REJECTION OF CLAIM 18 UNDER SECTION 103 IS IMPROPER.

Claim 18 was also rejected over the Boehringer reference in view of Cole. This rejection of claim 18 is improper for reasons in addition to the reasons presented for allowability of claims 10, 15 and 16 from which it depends.

Claim 18 requires that:

"each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit."

Rejection based on the Boehringer reference in view of Cole relies upon the Cole reference to show that each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit, but the Cole reference does not teach or suggest use of multiple devices and therefore the combination does not result in the invention of

claim 18. Further, it is believed that the combination required to meet the terms of these claims is a hindsight reconstruction of the prior art.

7D. EACH OF THE CLAIMS DEPENDING FROM CLAIMS 10 AND 20 AND REJECTED UNDER SECTION 102 DEFINES DISTINCT AND NON-OBVIOUS SUBJECT MATTER AND FURTHER DISTINGUISHES THE INVENTION OVER THE PRIOR ART.

CLAIM 11 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 11, which depends from claim 10 further distinguishes over the Boehringer reference, requiring, among other features, that the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least the second level. These features provide another novel combination.

CLAIM 12 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 12, which depends from claim 10 further distinguishes over the Boehringer reference, requiring, among other features, that the first unit includes a second region responsive to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least said one sensitivity level different than the first of the sensitivity levels. These features also provide another novel combination.

CLAIM 13 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 13, which depends from claim 12 further distinguishes over the Boehringer reference, requiring, among other features, that said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels. This feature also provides another novel combination.

CLAIM 14 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 14, which depends from claim 10 requires that the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels. This feature also provides another novel combination.

CLAIM 15 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 15, which depends from claim 10 requires that the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels. This feature also provides another novel combination.

CLAIM 16 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 16, which depends from claim 15 requires that the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels. This feature also provides another novel combination.

CLAIM 19 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 19, which depends from claim 10 requires that the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions. This feature also provides another novel combination.

CLAIM 21 FURTHER DISTINGUISHES OVER THE ART OF RECORD

Claim 21, which depends from claim 20, further requires that the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate. This feature also provides another novel combination.

7E. FURTHER REBUTTAL TO THE EXAMINER'S ARGUMENTS

At pages 12 and 13 of the Final Office Action the Examiner dismissed Appellant's distinctions, arguing in part that both the Boehringer reference and in the Kenjyou reference provide

"first and second samples to the plurality of test units, wherein **the samples can be provided from the same source at subsequent occasions**. Applicant does not specify what exactly is meant by "an occasion subsequent," and therefore, as long as both references teach applying the sample to the units one at a time, this anticipates a "subsequent occasion [Emphasis Added]."

Appellant respectfully disagrees with this characterization. Neither the Boehringer reference nor the Kenjyou reference have been shown to apply a sample from the same source at subsequent occasions. No where in the references is this even suggested. It is only the Appellant who teaches his concept.

As for the argument that the meaning of "an occasion subsequent to providing the first sample" has not been specified, this is incorrect. Support for this language is found in the specification and no more than the plain meaning of these words is needed in order to construe the claims. See, for example, the patent specification at page 4, lines 6 – 16. See, also, page 20, lines 2 – 15. Note, also, at page 20, lines 10 – 12, it is stated:

"...when samples are sequentially taken from the same source, the responses can indicate temporal changes in analyte concentration in the source."

Thus the meaning of providing, for example, a second sample subsequent to providing the first sample has a well-understood meaning in viewof the patent specification.

The examiner has also argued that the devices disclosed in the references "allow" for the claimed method. The possibility that a device of the prior art might be used to practice a novel method does not render the method anticipated. Indeed, the claimed methods may possibly be practiced with prior art devices. Yet it is well established that new methods of using known

devices are patentable subject matter. So it cannot follow that the references anticipate the claims merely because they disclose devices with which a novel method can be practiced.

The Examiner has also disagreed with Appellant's statement that neither of the references suggest providing multiple test devices, but the Examiner then agrees that they only disclose multiple regions on each device. There appears to be no disagreement on this latter point.

It is significant that neither of the references suggest providing multiple test devices. Appellant continues to contend that none of the prior art discloses multiple units or devices which receive analyte-containing samples taken from a source on different occasions. As the Examiner acknowledges, the prior art discloses multiple "units" connected together or connected to a main backing.

This feature of the prior art devices is consistent with the prior art use of such devices, i.e., placing portions of the same sample on different regions within the same device, e.g., in order to more clearly determine a qualitative or quantitative assay, such as by counting visible lines.

However, this feature of the prior art is not anticipatory of providing samples obtained from the same source on different occasions to determine whether each of the samples meets a predetermined level, e.g., to assess whether there is a temporal change in concentration.. Thus it is submitted that there is no basis to conclude that the claimed method is implied or otherwise suggested by the references.

7G. ALL OF THE CLAIMS SHOULD BE PASSED TO ISSUANCE.

Based on the foregoing, the Final Rejection as applied to every one of the claims is in error. Every one of the claims stands up to all of the art of record. Reversal is therefore requested so the claims may be passed to issuance.

8. CLAIMS APPENDIX - 37 CFR 41.37(c) (1) (viii).

A copy of the claims involved in this appeal is attached as a claims appendix under 37 CFR 41.37(c) (1) (viii).

9. EVIDENCE APPENDIX - 37 CFR 41.37(c) (1) (ix)

None is required under 37 CFR 41.37(c) (1) (ix).

10. RELATED PROCEEDINGS APPENDIX - 37 CFR 41.37(c) (1) (x)

None is required under 37 CFR 41.37(c) (1) (x).

Respectfully submitted,

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CERTIFICATE OF TRANSMISSION

I HEREBY CERTIFY that this Amended Appeal Brief is being FAXED to the U.S. Patent Office at 571-273-8300 (Central Fax Number) on this 1st day of May, 2007.

Ferdinand M. Romano

Ferdinand M. Romano

Serial No. 10/530,464

Atty. Doc. No. 10442-004

APPENDIX OF CLAIMS ON APPEAL

1. A method for monitoring temporal changes of analyte levels in a source comprising:

providing multiple unitary test devices, each unitary test device including a plurality of regions, each region responsive at a different sensitivity level to indicate presence of the analyte in the source;

bringing a sample from the source into contact with a first of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the first test device;

subsequently bringing a different sample from the same source into contact with a second of the unitary test devices to determine whether the source contains a level of analyte sufficient to induce a response thereto in one or more regions of the second unitary test device, said responses providing information about temporal change in analyte concentration.

10. A method for monitoring changes in analyte level of a source, comprising:

efining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source;

roviding a first test unit including a first region thereon responsive to the presence of analyte in the source at a first of the sensitivity levels;

roviding a second test unit including a first region thereon responsive to the presence of analyte in the source at a second of the sensitivity levels;

roviding a first sample from the source;

ringing the first sample into contact with the first unit to allow the first region thereon to indicate whether analyte is present in the sample at at least the first level;

roviding a second sample from the source on an occasion subsequent to providing the first sample; and

ringing the second sample into contact with the second unit to allow the first region thereon to indicate whether analyte is present in the second sample at at least the second level.

11. The method of claim 10 wherein the first unit includes a second region responsive to presence of the second level of analyte and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least the second level.

12. The method of claim 10 wherein the first unit includes a second region responsive to presence of one measurably distinguishable sensitivity level different than the first of the sensitivity levels and the step of bringing the first sample into contact with the first unit includes allowing said second region to indicate whether analyte is present in the sample at at least said one sensitivity level different than the first of the sensitivity levels.

13. The method of claim 12 wherein said one measurably distinguishable sensitivity level different than the first of the sensitivity levels is substantially the same as the second of the sensitivity levels.

14. The method of claim 10 wherein the second test unit includes a second region thereon responsive to the presence of analyte in the source at the first of the sensitivity levels.

15. The method of claim 10 wherein the step of providing the first test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

16. The method of claim 15 wherein the step of providing the second test unit includes forming thereon at least three regions each responsive to the presence of analyte in the source at a different one of the multiple measurably distinguishable sensitivity levels.

17. The method of claim 16 wherein the steps of providing the first and second test units are performed such that at least one of the three regions of the first unit and one of the three regions of the second unit are responsive to the presence of analyte in the source at substantially the same sensitivity level.

18. The method of claim 16 wherein each of the regions of the first unit is responsive to substantially the same level of analyte as one of the regions of the second unit.

19. The method of claim 10 wherein the step of defining multiple measurably distinguishable sensitivity levels each indicative of a different amount of analyte in the source is accomplished by forming at least the first regions.

20. A method for monitoring changes in analyte level of a source, comprising:
providing two or more test units each including multiple regions thereon, each region in each unit responsive to the presence of an analyte in the source at a sensitivity level measurably distinguishable from another region in the same test unit;
bringing a first sample from the source into contact with a first of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the sample at at least one of the levels; and
on an occasion subsequent to providing the first sample, bringing a second sample from the source into contact with a second of the units to allow one or more of the regions thereon to indicate whether the analyte is present in the second sample at at least one of the levels.

21. The method of claim 20 wherein the step of providing one of the test units includes adhesively mounting the multiple regions on a substrate.

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EVIDENCE APPENDIX

None.

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RELATED PROCEEDINGS APPENDIX

None